

**Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
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The Commonwealth of Massachusetts

TO: Massachusetts Pharmacies and Pharmacists

FROM: Madeleine Biondolillo, MD, Bureau Director
Iyah K Romm, Director of Policy, Health Planning, and Strategic Development

DATE: January 7, 2013 (revising prior memo dated December 31, 2012)

RE: **DELAY of Implementation of Section 4 of Chapter 244**, of the Acts of 2012
An Act Relative to Prescription Drug Diversion, Abuse, and Addiction

Chapter 244 of the Acts of 2012 (the Prescription Drug Omnibus), *An Act Relative to Prescription Drug Diversion, Abuse and Addiction* is designed to help prevent the diversion and abuse of prescription drugs. Most prominently, Chapter 244 requires a practitioner prescribing controlled substances to be enrolled in an established prescription monitoring program (PMP), requires all pharmacists to be trained in the use of the PMP through continuing education, establishes restrictions on filling of out-of-state prescriptions for Schedule II narcotics, and requires dissemination of educational materials on risks related to opiate drugs and addiction treatment resources to be distributed to consumers by pharmacists when dispensing a narcotic or controlled substance contained in schedule II or III.

Effective January 1, 2013, Section 2 of Chapter 244 stipulates that if a person registered to distribute controlled substances discovers a theft or loss of controlled substances that requires the filing of DEA Form 106 with the United States Drug Enforcement Administration, the person shall simultaneously file a copy of that form with the Massachusetts State Police. If a person registered to dispense controlled substances discovers a theft or loss of controlled substances that requires the filing of DEA Form 106 with the United States Drug Enforcement Administration, the person shall simultaneously file a copy of that form with the police department in the city or town wherein the theft or loss is alleged to have occurred and to Massachusetts State Police. This does not eliminate reporting requirements to the Massachusetts Drug Control Program, the Massachusetts Board of Registration in Pharmacy, or with the United States Drug Enforcement Administration.

Contact information for forms to be sent to local law enforcement should be determined at the local level by each pharmacy licensed in the Commonwealth. Forms to be sent to the Massachusetts State Police should be submitted by hardcopy, electronic mail, or fax as follows:

Hard Copy:
Massachusetts State Police
6 West St.
Norwell, MA. 02061
Attn: Sergeant David McQueeney

E-mail:
david.mcqueeney@massmail.state.ma.us

Fax:
781-659-0145

Section 4 of Chapter 244 restricts the filling of out-of-state schedule

II narcotic prescriptions. This section was initially enacted to be effective January 1, 2013.

Due to recent changes aimed at easing the transition of the implementation of this section, the effective date has been pushed back to May 1, 2013. Once this section becomes effective, pharmacies may fill out-of-state prescriptions for Schedule

II narcotics¹ (as defined under 21 CFR 1308.12) only if issued by providers licensed in Maine or in a state contiguous with the Commonwealth (Rhode Island, Connecticut, New York, Vermont, and New Hampshire), and have been issued within the preceding five (5) days. This geographic limitation will apply only to Schedule II narcotic substances. This section will not change the filling of non-narcotic Schedule II prescriptions issued by out-of-state providers, nor the filling of schedule II prescriptions issued by Massachusetts providers.

Section 5 of Chapter 244 requires that the Department of Public Health develop a pamphlet for consumers relative to narcotic drugs. The pamphlet shall include educational materials on risks related to opiate drugs and addiction treatment resources. It will be distributed to pharmacies, not including institutional pharmacies. A pharmacist shall distribute the pamphlet to consumers when dispensing a narcotic or controlled substance contained in schedule II or III. The Department is actively developing such materials, which will be disseminated electronically in early 2013.

Section 6 of Chapter 244 requires that pharmacies registered to dispense federally controlled substances, not including institutional pharmacies or pharmacy departments except as otherwise provided in 247 CMR, post a sign at least 4 by 5 inches stating "Lock boxes for securing your prescription medications are available at this pharmacy". This new law deletes the requirement that lock boxes shall be available within 50 feet of the pharmacy counter. The new law additionally deletes the requirement that pharmacies need to encourage consumers buying over-the-counter or prescription medications to purchase one. Such signage shall be displayed on or near the pharmacy counter. "Lock boxes" are defined as a box with a locking mechanism that cannot be tampered with or opened without extreme force

Section 7 of Chapter 244, effective July 1, 2013, requires prescribers to utilize tamper-resistant prescription forms consistent with federal requirements for Medicaid. Emergency amendments to 105 CMR 721.020: *Standards for Prescription Format and Security in Massachusetts*, have been promulgated by the Massachusetts Public Health Council and will be codified in the coming months prior to the effective date.

¹ <http://www.deadiversion.usdoj.gov/schedules/index.html>

Section 8 of Chapter 244, effective January 1, 2013, requires that the Board of Pharmacy promulgate regulations requiring continuing education (CE) for pharmacists specific to training in the use of the prescription monitoring program (PMP). The Board will be considering such amendments in coming months, and all pharmacists should anticipate additional guidance later this spring, with an expectation of a one-time continuing education requirement no later than December 31, 2014.

Section 19 of Chapter 244 requires that DPH notify pharmacists of the opportunity to use the PMP, no later than January 1, 2013. The Department is actively developing such materials, which will be disseminated electronically in early 2013.

Finally, Section 21 of Chapter 244 requires that the Department convene a joint policy working group to investigate and study best practices, including those in education, prevention, screening, tracking, monitoring and treatment to promote safe and responsible opioid prescribing and dispensing practices for acute and chronic pain with the goal of reducing diversion, abuse and addiction and protecting access for patients suffering from acute and chronic pain.